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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,192	03/01/2002	David W. Morris	PP23696.0001/20366-035001	7201

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
12/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/087,192	MORRIS ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/25/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,21,22 and 24-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,21,22 and 24-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/25/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments and Argument

1. Claims 11, 21, 22 and 24-39 are pending.

Claim 40 has been cancelled.

Claims 11, 21, 34 and 39 have been amended.

Claims 11, 21, 22 and 24-39 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Grounds of Rejection

Claim Rejections - 35 USC § 112

3. The ***NEW MATTER REJECTION*** of claims 11, 21, 22 and 24-39 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicants' arguments. Claim 39 has been cancelled.

4. The rejection of claim 39 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants" amendment to the claim.

Claim Rejections - 35 USC § 102

5. The rejection of claims 11, 21, 22 and 24-38 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2004/0038207 A1 (filed September 14, 2001) is withdrawn in light of Applicants' amendment.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the specification fails to describe the genus of polynucleotides reading on a single nucleotide sequence which shares at least 98% sequence identity to a polynucleotide sequence comprising SEQ ID NO: 1175 that are also diagnostic of colon, breast or prostate cancers. Therefore, the specification lacks adequate written description for the broadly claimed methods. The specification fails to provide adequate written description of the genus of polynucleotide sequences that are diagnostic of cancer.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must

convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

For a claim drawn to a genus, the written description requirement may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A "representative number of species" means that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus (see Official Gazette 1241 OG 174, January 30, 2001). In the instant case, there is substantial variation in the genus for the claims that recites "...*a nucleotide sequence* having at least 98% sequence identity to a sequence of SEQ ID NO: 1175", the specification also fails to provide support because there is not even one representative species of diagnostic polynucleotide sequence that has been shown to be diagnostic of any type of cancer.

Therefore, applicant does not appear to be in possession of the broadly claimed methods.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 11, 21, 22 and 24-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Sikut et al. (Biochemical and Biophysical Research Communications 238: 612-616, 1997/ IDS reference AG submitted November 25, 2008). Sikut discloses a method of detecting CD43 (also art known as leukosialin and sialophorin) in colon adenoma and carcinomas tissues utilizing Western blot analysis and immunohistochemistry, see abstract; and page 613 Table 1. Absent evidence to the contrary the CD43 molecule disclosed in Sikut is the same as SEQ ID NO: 1175.

10. Claims 22, 24-29 and 31-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Sikut et al. (Int. J. Cancer 82(1): 52-58, July 2, 1999/ IDS reference AH submitted November 25, 2008). Sikut discloses a method of detecting CD43 (also art known as leukosialin and sialophorin) in colon adenoma and carcinomas tissues utilizing Western blot analysis, immunoprecipitation and immuno-histochemistry, see abstract. Absent evidence to the contrary the CD43 molecule disclosed in Sikut is the same as SEQ ID NO: 1175.

11. Claims 22, 24-29 and 31-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Topalovski et al. (Arch. Pathol. Lab Med. 123: 1208-1218, December 1999). Topalovski discloses a method of detecting CD43 in biopsies from primary breast lymphoma and secondary breast lymphoma, see page 1208, Results and Materials...sections.

12. Claims 22, 24-29 and 31-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Aguilera et al. (Mod. Pathol. 13(6): 599-604, 2000). Aguilera discloses a method of detecting CD43 breast cancers utilizing immunohistochemistry, see page 299, Immunohistochemistry section; Results section beginning on page 600, particularly Cases 1 and 3; page 604, Table 3.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 11, 21, 22 and 24-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sikut et al. (Biochemical and Biophysical Research Communications 238: 612-616, 1997/ IDS reference AG submitted November 25, 2008), and further in view of U.S. Patent Application Publication number 2004/0038207 A1 (filed September 14, 2001). The teachings of Sikut have been presented in the 102(b) rejection. Sikut

does not teach the hybridization of a polynucleotide that hybridizes under the designated hybridization conditions set forth in claim 39 with SEQ ID NO: 1175.

However, U.S. Patent Application Publication number 2004/0038207 A1 teaches the expression of sialophorin and a method of hybridization, see page 1, sections 0017 and 0018; Examples 1 and 7; and page 4, sections 0056-0058. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the teachings of both documents in order to effectively diagnose colon cancer using the methodologies cited therein using the hybridization criteria set forth in the claim. Furthermore, one of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the listed teachings in the patent application publication the method implementing a range of washes and stringencies is routine in experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955).

15. Claims 11, 21, 22 and 24-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sikut et al. (Int. J. Cancer 82(1): 52-58, July 2, 1999/ IDS reference AH submitted November 25, 2008), and further in view of U.S. Patent Application Publication number 2004/0038207 A1 (filed September 14, 2001). The teachings of Sikut have been presented in the 102(b) rejection. Sikut does not teach the comparison of a tumorous patient sample with a normal sample, nor the hybridization of a

polynucleotide that hybridizes under the designated hybridization conditions set forth in claim 39 with SEQ ID NO: 1175.

However, U.S. Patent Application Publication number 2004/0038207 A1 teaches the expression of sialophorin between tumor samples and normal samples and a method of hybridization, see page 1, sections 0017 and 0018; Examples 1 and 7; and page 4, sections 0056-0058. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the teachings of both documents in order to effectively diagnose colon cancer using the methodologies cited therein using the hybridization criteria set forth in the claim. Furthermore, one of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the listed teachings in the patent application publication that comparison between same type tissues and the method implementing a range of washes and stringencies is routine in experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955).

16. Claims 11, 21, 22 and 24-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aguilera et al. (Mod. Pathol. 13(6): 599-604, 2000), and further in view of U.S. Patent Application Publication number 2004/0038207 A1 (filed September 14, 2001). The teachings of Aguilera have been presented in the 102(b) rejection. Aguilera does not teach the comparison of a tumorous patient sample with a normal

sample, nor the hybridization of a polynucleotide that hybridizes under the designated hybridization conditions set forth in claim 39 with SEQ ID NO: 1175.

However, U.S. Patent Application Publication number 2004/0038207 A1 teaches the expression of sialophorin between tumor samples and normal samples and a method of hybridization, see page 1, sections 0017 and 0018; Examples 1 and 7; and page 4, sections 0056-0058. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the teachings of both documents in order to effectively diagnose breast cancer using the methodologies cited therein using the hybridization criteria set forth in the claim. Furthermore, one of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the listed teachings in the patent application publication that comparison between same type tissues and the method implementing a range of washes and stringencies is routine in experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955).

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, Monday through Saturday with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
22 December 2008

/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643